

Annexure II

Regulations, Syllabus and Scheme of Examination

of

**DBT SPONSORED ONE YEAR POST M.Sc., ADVANCED
DIPLOMA COURSE IN
MOLECULAR DIAGNOSTICS**



DEPARTMENT OF BIOTECHNOLOGY

(DST-FIST Sponsored Department)

Alagappa University

(A State University Accredited with “A” Grade)

Karaikudi – 630 003

**DEPARTMENT OF BIOTECHNOLOGY
ALAGAPPA UNIVERSITY**

**DBT SPONSORED ONE YEAR POST M.Sc., ADVANCED DIPLOMA COURSE IN
MOLECULAR DIAGNOSTICS**

Preamble

Early detection of pathogens and genetic defects is of prime concern to the medical community. As the conventional approach for detecting diseases, which is characterized by examining their unique morphologic, biochemical, immunologic features and karyotyping, is time consuming and labor intensive, “Molecular Diagnosis”, (demonstrating the presence of nucleotide sequences of the pathogen or the genetic disorder) is the need of the hour. Molecular Diagnosis will pave way for rapid and accurate identification of the disease and disease causing agents which in turn will lead to prompt and proper treatment of various life threatening diseases. Therefore a One Year Post M.Sc., Advanced Diploma Course in Molecular Diagnostics is envisaged to impart hands on training in the field of molecular diagnostics to candidates with life sciences background. This course would pave the way for human resource development for future employment in hospitals, clinical laboratories, biotechnological/ pharmaceutical industries, R&D institutions and academic institutions. This programme is unique in which the students would get intensive training in theoretical and experimental approaches in molecular diagnosis. The students will also carry out independent Project Work for one semester.

In the first semester, advanced theory papers (Fundamentals of Molecular Diagnostics and Methods and Applications of Molecular Diagnostics) and laboratory courses (Lab I- Methods in Molecular Biology and Lab-II- Molecular Diagnostics) will be offered. In the second semester, the students will carry out independent full-time Project Work. The findings of the Project Work will be compiled by the student and submitted in the form of a Dissertation.

1. Eligibility for admission:

A first class M. Sc., Degree in Life Sciences (Biotechnology, Botany, Zoology, Biochemistry, Microbiology, Genomic Sciences), Agriculture/Veterinary Sciences/ Fisheries Sciences / Pharmacy or M. Tech., in Biotechnology/Life Sciences or equivalent (Minimum marks for SC/ST candidates is 50%).

2. Mode of Selection:

Selection will be made based on the marks scored in the All India Level Entrance Examination and Reservation Policy stipulated by the Government of India. A total of 20 students will be selected each year.

3. Counseling:

Faculty Members and the instructors for each course will be the overall counselors of that course.

4. Course structure:

The course shall extend over a period of 12 months divided into two semesters.

5. Evaluation:

- I. Mark system follows the University regulations. Each Theory course carries 4 credits. Each Lab course carries 6 credits.
- II. For each theory/lab course, 25% of the total marks will be allotted to internal assessment, and the rest (75%) for final University examination. The internal assessment for each course will be carried out by the course instructor.

The break up for Continuous Internal Assignment will be as follows:

a) For Theory Paper

Average of two tests	15 marks
Seminar/Quiz	5 marks
Assignment	5 marks

Total	25 marks

b) For Lab Course

Average of two tests	10 marks
Performance of experiments	5 marks
Presentation of results and viva	5 marks
Maintenance of records	5 marks

Total	25 marks

III. Project Work evaluation:

a) Seminar (Power Point) Presentation of a Journal Paper	50 marks
b) Project Viva	150 marks
c) Dissertation	200 marks

Total	400 marks

Seminar given by the student will be evaluated by a committee composed of all course teachers. Evaluation of Project Viva and Dissertation will be done by the course teachers and External Examiner(s).

6. Tabulation of final results:

- I. The marks obtained in each course, internal and University Examination will be entered separately.
- II. A candidate shall be declared to have passed in each course if he/she secures not less than 40% marks in the University Examination and 40% marks in the Continuous Internal Assessment and not less than 50% in the aggregate, taking CIA and University Examination marks together.
- III. The final result of the candidate shall be based only on CGPA earned by the candidate.
- IV. Successful candidates passing the examinations and earning CGPA between 6.01 and 7.50 shall be declared to have passed in First Class and those who earned CGPA between 5.00 and 6.00 shall be declared to have passed in Second Class.
- V. Candidates earning CGPA between 7.51 and 9.00 in the first appearance within the prescribed duration of the programme shall be declared to have passed in First Class with Distinction and those who earned CGPA 9.01 and above in the first appearance within the prescribed duration of the programme shall be declared to have passed in First Class – Exemplary.

7. Fees structure:

The Fee Structure for the One Year Post M. Sc., Advanced Diploma Course in Molecular Diagnostics (Regular) shall be as follows:

Fee Structure		
a)	Admission fee	Rs. 100
b)	Recognition fee	Rs. 100(Rs. 200 in the case of other University students)
c)	Special fees	Rs. 1600
d)	Tuition fee	Rs. 3000
e)	P.T.A. fee	Rs. 100
f)	Alumni Association fee	Rs. 100
g)	NSS Fee	Rs. 30
h)	Refundable Caution Deposit	Rs. 500

The income generated through fees shall be spent for running the course in an effective and efficient manner.

8. Course Organization and Scheme of evaluation

S. No	Code	Name of the Course	Credits	Marks		
				CIA	ESE	Total
SEMESTER – I						
1.	951101	Fundamentals of Molecular Diagnostics	4	25	75	100
2.	951102	Methods in Molecular Diagnostics	4	25	75	100
3.	951103	Lab I: Molecular Biology	8	25	75	100
4.	951104	Lab II: Molecular Diagnostics	8	25	75	100
SEMESTER – II						
5.	951201	Project Work	24	400		400
Total			48			800

9. Details of Course Content:

SEMESTER – I

951101: FUNDAMENTALS OF MOLECULAR DIAGNOSTICS

UNIT-1

Historical introduction. Infection – mode of transmission in infections, factors predisposing to microbial pathogenicity, types of infectious diseases. Philosophy and general approach to clinical specimens, Sample collection- method of collection, transport and processing of samples. Interpretation of results. Normal microbial flora of the human body. Nosocomial infections. Host - Parasite relationships.

UNIT-2

Pathogenicity and diagnosis of infection caused by *Streptococcus*, *Coliforms*, *Salmonella*, *Shigella*, *Vibrio*, and *Mycobacterium*. Diagnosis of fungal infections. Major fungal diseases: Dermatophytoses, Candidiasis and Aspergillosis.

UNIT-3

Diagnosis of DNA and RNA viruses. Pox viruses, Adenoviruses, Rhabdo Viruses, Hepatitis Viruses and Retroviruses. Diagnosis of Protozoan diseases: Amoebiasis, Malaria, Trypanosomiasis, Leishmaniasis. Study of helminthic diseases- *Fasciola hepatica* and *Ascaris lumbricoides*. Filariasis and Schistosomiasis.

UNIT-4

Medical Genetics: Organization of human genome, Human Genome Project, Identifying human disease genes. Cancer genetics- oncogenes, tumour suppressor genes. Gene therapy and other molecular based therapeutic approaches. Genes in pedigree. Genetic Counselling.

UNIT-5

Genetic disorders: Sickle cell anaemia, Duchenne muscular Dystrophy, Retinoblastoma, Cystic Fibrosis and Sex – linked inherited disorders. Neonatal and Prenatal disease diagnostics. Gender identification using amelogenin gene locus. Amplification of Y chromosome specific Short Tandem Repeats (Y-STR). Analysis of mitochondrial DNA for maternal inheritance.

REFERENCES

1. Medical Microbiology (1997), Edited by Greenwood, D, Slack, R and Peutherer, J, ELST Publishers.
2. Parasitology (1997), Chatterjee K.D, Chatterjee Medical Publishers.
3. Bailey & Scott's Diagnostic Microbiology (2002), Betty A. Forbes , Daniel F. Sahm, Alice S. Weissfeld , Ernest A. Trevino, Published by C.V. Mosby
4. Jawetz, Melnick, & Adelberg's Medical Microbiology (2004), Geo F. Brooks, Stephen A. Morse, Janet S. Butel.
5. Fundamentals of Molecular Diagnostics (2007). David E. Bruns, Edward R. Ashwood, Carl A. Burtis. Saunders Group.
6. Henry's Clinical Diagnosis And Management By Laboratory Methods (2007) Mcpherson
7. Molecular Diagnostics: Fundamentals, Methods & Clinical applications (2007). Lele Buckingham and Maribeth L. Flaws
8. Molecular Diagnostics for the Clinical Laboratorian 2Ed. 2006, W.B. Coleman. Humana Press.
9. Molecular Pathology in Clinical Practice (2007). D. G. B. Leonard.
10. Microbial Functional Genomics (2004) by J.Zhou, D.K. Thomson. Y.Xu. J.M. Tiedje. J.Wiley & Sons Publishers.
11. Expert Review of Molecular Diagnostics

951102: METHODS IN MOLECULAR DIAGNOSTICS

UNIT-1

Isolation and Purification of Nucleic acids- Principles and Methods. Molecular cloning, labeling of nucleic acids, hybridization.

UNIT-2

Nucleic acid amplification methods and types of PCR: Reverse Transcriptase-PCR, Real-Time PCR, Inverse PCR, Multiplex PCR, Nested PCR, Alu-PCR, Hot-start, *In situ* PCR, Long-PCR, PCR-ELISA, Arbitrarily primed PCR, Ligase Chain Reaction.

UNIT-3

Applications of PCR- PCR based microbial typing: Eubacterial identification based on 16S rRNA sequences- Amplified Ribosomal DNA Restriction analysis (ARDRA)-Culture independent analysis of bacteria- DGGE and TRFLP. Molecular diagnosis of fungal pathogens based on 18S rRNA sequences- Detection of viral pathogens through PCR. RAPD for animal and plants- PCR in forensic science- AmpFLP, STR, Multiplex PCR- Determination of Paternity- Human identification and sex determination.

UNIT-4

Automated DNA sequencing- Principles, Methods and Instrumentation- Advances in DNA sequencing- Pyrosequencing- Microarrays- Personalised Medicine- Pharmacogenomics.

UNIT-5

Proteomics- Clinical Proteomics. Good Laboratory Practices. Different Levels of Biosafety, Containment Levels for rDNA experiments. Biosafety aspects of transgenic plants and germplasm.

REFERENCES

1. Genes VIII (2004) by B. Lewin, Oxford University Press.
2. An Introduction to Genetic Analysis (2000) by A.J.F. Griffiths, J.H. Miller, D.T. Suzuki, R.C. Lewontin and W.M. Gelbart, W.H. Freeman, New York.
3. Molecular Biology of the Gene (2004) by J.D.Watson, Tania A baker, Stephen P. Bell, Alexander Gann, Michael Levine, Richard Losick, Pearson Education Pte. Ltd. (Singapore).
4. Essentials of Molecular Biology (1998) by G. M. Malacinski and D. Friefelder, Jones & Bartlett Publishers.
5. rDNA safety guidelines- Government of India, Ministry of Science and Technology, Dept.of Biotechnology, New Delhi.
6. rDNA safety guidelines & regulations-Government of India, Ministry of Science and Technology, Dept.of Biotechnology, New Delhi.
7. An Introduction to Forensic DNA Analysis (2002) Rudin, N and Inman, K. CRC Press.
8. Forensic DNA Typing. Biology, Technology and Genetics of STR markers (2005) John M. Butler, Elsevier Academic Press, Amsterdam.
9. Molecular Diagnostics: Fundamentals, Methods & Clinical applications (2007). Lele Buckingham and Maribeth L. Flaws.
10. Fundamentals of Molecular Diagnostics (2007). David E. Bruns, Edward R. Ashwood, Carl A. Burtis. Saunders Group.
11. Expert Review of Proteomics and Molecular Diagnostics (Journals)

951103: LAB I – MOLECULAR BIOLOGY

UNIT-1

Isolation of Genomic DNA from microbe (*E.coli*), Plant (*Bacopa monnieri*), Animal (*C. elegans*) and Human (*Peripheral Blood*). Isolation of Metagenome (sediment/soil). Plasmid DNA isolation by Alkaline lysis and Boiling method. Quality / Quantity checking of Nucleic acids by a) UV Spectrophotometer and b) Agarose Gel Electrophoresis. Restriction analysis.

UNIT-2

Molecular Cloning- Ligation- Competent cell preparation- Transformation- selection of recombinants (Blue white selection)- Confirmation of recombinants by gel electrophoresis.

UNIT-3

Construction of Genomic DNA Library- Metagenomic DNA Library using Fosmid vector- Screening of recombinants- Nucleic acid labeling and Southern Hybridization- Automated DNA sequencing (Demo).

UNIT-4

Polymerase Chain Reaction - Isolation of RNA by TRIZOL method from prokaryote (*E.coli*) and eukaryote (*C.elegans*). Reverse Transcriptase- PCR. Real Time PCR (Demo).

UNIT-5

Proteome analysis- Characterization of Proteins by SDS-PAGE and 2D Gel Electrophoresis (Demo) - Purification of proteins by FPLC (Demo)- Immunological methods: Agglutination (ABO/Bacterial), Precipitation, Immunodiffusion, Immuno-electrophoresis, ELISA and Western blotting.

REFERENCES

1. Molecular Cloning: Laboratory Manual (2001) Sambrook, J., Russell, D.W., Sambrook, J.
2. Analyzing DNA. A Laboratory Manual (1997) Edited by Bruce Birren, Eric D Green, Sue Klapholz, Richard M. Myers and Jane Roskams, Cold Spring Harbor Laboratory Press.
3. Manual of Clinical Laboratory Immunology (2002) Edited by N. R. Rose, R. G. Hamilton and B. Detrick, ASM Press.
4. Hand book of Experimental Immunology Vol.I & II (1986). Weir, D.M.
5. Molecular Diagnostics: Fundamentals, Methods & Clinical applications (2007). Lele Buckingham and Maribeth L. Flaws.
6. Fundamentals of Molecular Diagnostics (2007). David E. Bruns, Edward R. Ashwood, Carl A. Burtis. Saunders Group.
7. Molecular Diagnostics for the Clinical Laboratorian 2Ed. 2006, W.B. Coleman. Humana Press.
8. Molecular Pathology in Clinical Practice (2007). D. G. B. Leonard.
9. Gene Function Analysis (2007). M. F. Ochs.
10. Expert Review of Proteomics and Molecular Diagnostics (Journals)

951104. LAB II – MOLECULAR DIAGNOSTICS

UNIT-1

- A) Identification of human bacterial pathogens by Polymerase chain reaction
- B) PCR based diagnosis of plant bacterial pathogen
- C) Culture independent analysis of microbes by DGGE and TRFLP.

UNIT-2

- A) Detection of viral infections in shrimp by PCR
- B) Molecular detection and characterization of DNA virus
- Hepatitis B virus
- C) Molecular diagnosis of Human Immunodeficiency virus (HIV) by RT- PCR (Demo)
- D) Molecular diagnosis of Human Immunodeficiency virus (HIV) by Western Blotting (Demo)

UNIT-3

- A) Genotypic characterization of fungal pathogens
- B) Molecular diagnosis of parasitic disease
- C) Detection of transgenes in GMOs
- C) Application of RAPD in plant breeding.

UNIT-4

- A) Amplification of Short Tandem Repeats (STR)/Microsatellites.
- B) Multiplex STR PCR (Demo).
- C) Single strand conformation polymorphism (SSCP) analysis.
- D) HLA typing and tissue transplantation matching (Demo)
- E) Microarrays for pathogen detection and SNP studies (Demo).
- F) Bioinformatic tools for genome and proteome analysis.

UNIT-5

Molecular Diagnosis of human genetic disorders

- A) Beta thalassemia
- B) Checking of p53 gene polymorphism for susceptibility to cancer
- C) Down's Syndrome
- D) Retinitis pigmentosa
- D) Human identification and paternity determination (simulated) by VNTR Probes

REFERENCES

1. Molecular Microbiology: Diagnostic Principles and Practice. (2004) Edited by Persing, D. H, Tenover, F. C, Versalovic, J, Tang, Y.W, Unger, E.R, Relman, D. A, and White, T. J. ASM Press.
2. Mutation Detection: A Practical approach. (1998) Edited by Cotton, R. G. H, Edkins, E and Forrest, S. IRL Press.
3. Molecular Cloning: Laboratory Manual (2001) Sambrook,J., Russell, D.W., Sambrook,J. CSHL Press.
4. Clinical Applications of PCR (2 Ed.) 2006. Y. M. Dennis Lo, Rossa W. K. Chiu and K. C. Allen Chan
5. Molecular Pathology in Clinical Practice (2007). D. G. B. Leonard.
6. Molecular Diagnostics: Fundamentals, Methods & Clinical applications (2007). Lele Buckingham and Maribeth L. Flaws.
7. Fundamentals of Molecular Diagnostics (2007). David E. Bruns, Edward R. Ashwood, Carl A. Burtis. Saunders Group.
8. Expert Review of Proteomics and Molecular Diagnostics (Journals)

SEMESTER – II

951201: PROJECT WORK

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POST M.Sc., ADVANCED DIPLOMA IN MOLECULAR DIAGNOSTICS

Question Paper pattern for both Theory and Lab Courses (Written):

Part – A

Ten questions (No choice)
(Two questions from each Unit)

10 x 2 = 20 marks

Part – B

Five questions (either or type)
(One question from each Unit)

5 x 5 = 25 marks

Part – C

Three questions out of five

3 x 10 = 30 marks
(One question from each Unit)